North Shore-Long Island Jewish Health System

Institutional Review Board
FWA #00002505
Office of the Human Research Protection Program
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New Hyde Park, NY 11042
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To: Keith Sultan, MD
Gastroenterology
North Shore University Hospital
300 Community Drive
Manhasset, NY 11030

From: Hallie Kassan, MS, CIP
Director, Office of the Human Research Protection Program

Date: Thursday, June 25, 2015

RE: **IRB #:** 15-076
Protocol Title: Endoscopic and Clinical Findings of Histopathologically Confirmed Mycophenolate Mofeti-Induced Colitis
Modification Approval Date: 6/25/2015

Dear Dr. Sultan:

This is to advise you that the submission received 6/16/2015 for the above referenced study was reviewed by the Institutional Review Board and the following determination was made:

Expedited Approval for the following:

1. Revised Application for Chart Review - Version 6/25/15.

Please note: **If consent forms have been revised with this modification, please make sure to use the newly stamped consent forms going forward.**

This modification was reviewed in accordance with 45 CFR 46.110(b) and 21 CFR 56.110(b). All conditions of approval previously established by the IRB for this research project continue to apply. The Institutional Review Board - Committee will be notified of this action at its meeting on 6/30/2015.

All studies are subject to audits by the Office of Research Compliance and/or Institutional Review Board to confirm adherence to institutional, state, and federal regulations governing research.

NOTE: This approval is subject to recall if at any time the conditions and requirements as specified in the IRB Policies and Procedures are not followed (see next page and web site: http://www.northshorelij.com/body.cfm?ID=2804)

NOTE: All IRB Policies and Procedures must be followed, including the following:

1. Using only IRB-approved consent forms, questionnaires, letters, advertisements, etc. in your research.
2. Submitting any modifications made to the study for IRB review prior to the initiation of changes except when necessary, to eliminate apparent, immediate hazards to the subject.
1. Reporting unanticipated problems involving risk to subjects or others.
2. Renewing the study at the interval set by the Institutional Review Board. You should submit a progress report to the Institutional Review Board at least two months prior to expiration of the study. Failure to receive notification that it is time to renew does not relieve you of your responsibility to provide the IRB with the Progress Report in time for the request to be processed and approved prior to your expiration date.
3. Prior to implementation, any changes made to studies utilizing TAP must have COPP, as well as IRB approval.

IMPORTANT REMINDER: The International Committee of Medical Journal Editors (ICMJE) requires registration of clinical research studies meeting specific guidelines prior to publication. Please see ICMJE requirements for registration of clinical trials at http://www.icmje.org. Our organization account is in the name of the North Shore-Long Island Jewish Health System. To register your trial: http://prsinfo.clinicaltrials.gov